

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	David McMorrow, Henrick Hansen and Tom McHale
Application No.:	10/087303
Filed:	February 28, 2002
For:	BALLOON FOLDING APPARATUS, METHODS AND PRODUCTS
Examiner:	Ryan Severson
Group Art Unit:	3731

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-9719-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application, in which claims 21-24, 29-30, 39-41 and 45-47 were rejected in the Final Office Action mailed June 23, 2010. A Notice of Appeal was filed on August 18, 2010. This brief is submitted in accordance with 37 C.F.R. § 41.37. The fees required under 37 C.F.R. § 41.20, and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

A Table of Contents is included on page 2 of this document.

TABLE OF CONTENTS

Identification Page.....	cover page
(i) Real Party in Interest	3
(ii) Related Appeals and Interferences	4
(iii) Status of Claims.....	5
(iv) Status of Amendments	6
(v) Summary of Claimed Subject Matter.....	7
(vi) Grounds of Rejection to be Reviewed on Appeal	10
(vii) Argument	11
Issue 1: Whether the Examiner erred in rejecting claims 21-24, 29-30, 39-41, and 45-47 under 35 U.S.C. § 103(a) over Butaric et al (US 6,033,380) in view of Bersin (US 5,383,856).....	
(viii) Claims Appendix.....	21
(ix) Evidence Appendix.....	25
(x) Related Proceedings Appendix.....	26

(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc., One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

There are no related appeals and interferences pending.

(iii) Status of Claims

Claims 21-25, 29-30, 39-41 and 43-47 are pending in the Application. Claims 25 and 43-44 were previously withdrawn. Claims 1-20, 26-28, 31-38 and 42 have been canceled. Claims 21-24, 29-30, 39-41 and 45-47 stand rejected and are the subject of this appeal.

(iv) Status of Amendments

All previously presented amendments have been entered.

(v) Summary of Claimed Subject Matter

Claim 21 recites a medical balloon 104 having a first end, a second end, a body portion longitudinally between the first end and the second end, and a balloon wall. FIGS. 1 & 2. The balloon 104 has a contracted condition and is expandable to an expanded condition. FIGS. 12 & 13. When the medical balloon is in its expanded state, the balloon wall is formed of a material and has an inner surface facing inward and an outer surface facing outward. FIG. 13. When the medical balloon 104 is in its contracted condition, the medical balloon has a central portion 112 and a plurality of structures 124 formed in the body portion and extending from the central portion disposed thereabout. FIG. 12; Specification, p. 4, l. 12-18; p. 8, l. 15-33. Each structure 124 comprises a base that is a double layer of the balloon wall, a first wing 118a wrapped continuously in a first direction circumferentially away from the base and about the central portion of the balloon to and terminating at a first terminating end and a second wing 118b wrapped continuously in a second direction, opposite the first direction, circumferentially away from the base and about the central portion of the balloon to and terminating at a second terminating end. FIG. 12; Specification, p. 8, l. 15-33. Each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure. FIG. 12; Specification, p. 8, l. 15-33. When the medical balloon is in its expanded condition, the body portion of the medical balloon has a circular cross- section in the location of the plurality of structures. FIG. 13.

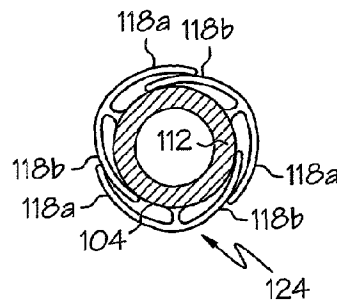


FIG. 12

Claim 27 recites a medical balloon 104 having a balloon wall, a contracted condition and expandable to an expanded condition. FIGS. 1, 2, 12, & 13. When the medical balloon is in its expanded condition, the balloon wall is formed of a material. FIG. 13. The medical balloon has an inner surface facing inward, an outer surface facing outward, and a circular cross-section. FIG. 13. In its contracted condition, the medical balloon has a central portion 112

and a plurality of structures 124 extending from the central portion. FIG. 12; Specification, p. 4, l. 12-18; p. 8, l. 15-33. The structures 124 each comprise a base that is a double layer of the balloon wall, a first wing 118a extending continuously in a first direction circumferentially away from the base and around the central portion to and terminating at a first terminating end, and a second wing 118b extending continuously in a second direction circumferentially away from the base and around the central portion to and terminating at a second terminating end. FIG. 12; Specification, p. 8, l. 15-33. There are a plurality of first wings and a plurality of second wings, wherein the first wings and the second wings extend around the central portion in opposite directions and wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure. FIG. 12; Specification, p. 8, l. 15-33.

Claim 41 recites a medical balloon 104 having a balloon wall, a contracted condition and expandable to an expanded condition. FIGS. 1, 2, 12, & 13. When the medical balloon 104 is in its expanded state, the medical balloon has a circular cross-section along its entirety. FIG. 13. The balloon wall is formed of a material and has an inner surface facing inward and an outer surface facing outward. FIG. 13. In its contracted condition, the balloon has a central portion 112 and a plurality of structures 124 extending from the central portion 112 disposed thereabout. FIG. 12; Specification, p. 4, l. 12-18; p. 8, l. 15-33. Each structure comprises a base that is a double layer of the balloon wall, a first wing 118a wrapped continuously in a first direction about the central portion of the balloon to and terminating at a first terminating end, and a second wing 118b wrapped continuously in a second direction, opposite the first direction, about the central portion of the balloon to and terminating at a second terminating end. FIG. 12; Specification, p. 8, l. 15-33. The base of each of the structures 124 is positioned in the second direction relative to the first terminating end and in the first direction relative to the second terminating end such that each base of the plurality of structures 124 is positioned circumferentially between the first terminating end and the second terminating of the structure 124 that corresponds to the base. FIG. 12; Specification, p. 8, l. 15-33. Each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure. FIG. 12; Specification, p. 8, l. 15-33.

Claim 45 depends from claim 21 and recites that when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the

structures is prone and face to face without obstruction to the material of the balloon wall of the central portion. FIG. 12.

Claim 46 depends from claim 29 and recites that when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the structures is prone and face to face without obstruction to the material of the balloon wall of the central portion. FIG. 12.

Claim 47 depends from claim 41 and recites that when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the structures is prone and face to face without obstruction to the material of the balloon wall of the central portion. FIG. 12.

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether the Examiner erred in rejecting claims 21-24, 29-30, 39-41, and 45-47 under 35 U.S.C. § 103(a) over Butaric et al (US 6,033,380) in view of Bersin (US 5,383,856).

(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claims 21-24, 29-30, 39-41, and 45-47 under 35 U.S.C. § 103(a) over Butaric et al (US 6,033,380) in view of Bersin (US 5,383,856)

The Examiner erred in rejecting claims 21-24, 29-30, 39-41 and 45-47 under 35 U.S.C. § 103(a) over Butaric et al (US 6,033,380) in view of Bersin (US 5,383,856) because the references do not teach or suggest all of the claim limitations of the rejected claims and there is no reasonable expectation of success in the combination of the references.

1. The references do not teach or suggest all of the limitations of the claimed invention as asserted by the Examiner, particularly with respect to the Bersin reference.

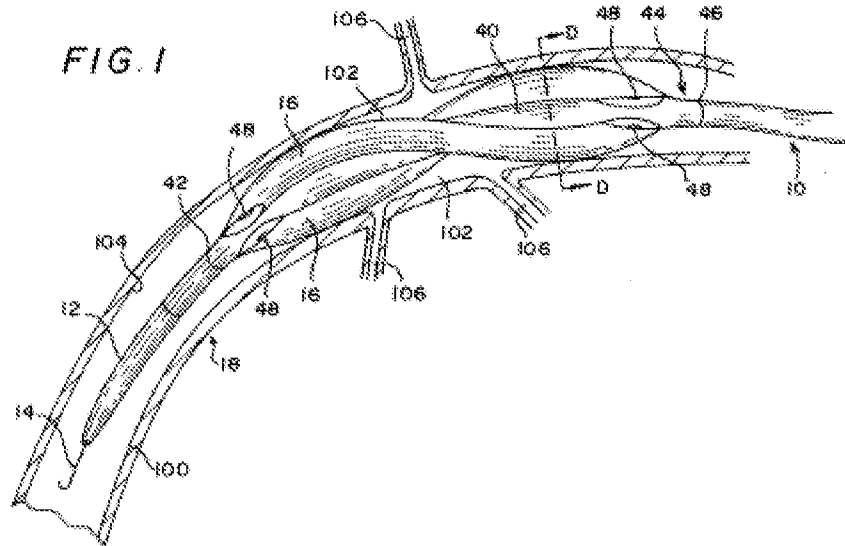
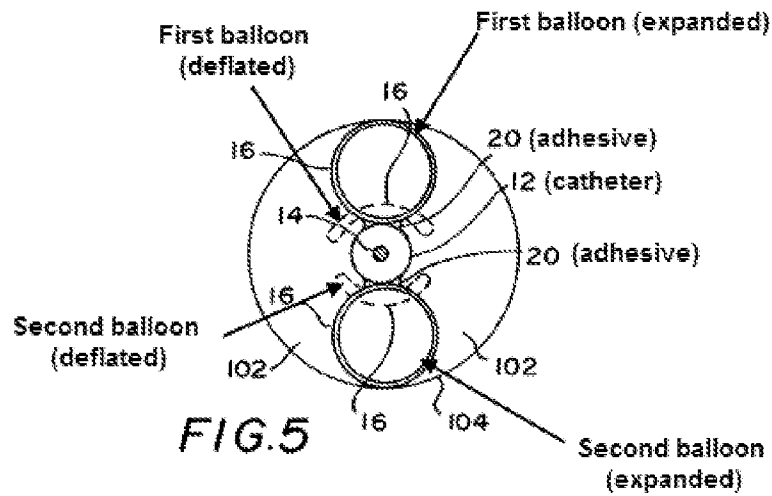
An obviousness rejection requires a suggestion of all limitations in a claim. *See CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Independent claim 21 recites, in pertinent part, a medical balloon in a contracted condition having:

“a central portion and a plurality of structures formed in the body portion and extending from the central portion disposed thereabout, each structure comprising a base, wherein the base is a double layer of the balloon wall, a first wing wrapped continuously in a first direction circumferentially away from the base and about the central portion of the balloon to and terminating at a first terminating end and a second wing wrapped continuously in a second direction, opposite the first direction, circumferentially away from the base and about the central portion of the balloon to and terminating at a second terminating end, wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure.”

The Examiner erroneously asserts that Bersin “teaches a balloon having multiple structures (16, see figure 5), where the structures when contracted have a T-shape (as shown in phantom lines in figure 5) with first and second wings extending in opposite directions.” Final Office Action, p. 3, ¶ 4.

First, Bersin does not teach a **single** balloon having the required plurality of structures. Instead, Bersin teaches two separate, diametrically opposed balloons 16 bonded to the outer surface of a catheter with adhesive 20. *See* col. 3, l. 66-68; col. 4, l. 1-16; FIGS. 1, 2 & 5 (FIG 1 is reproduced below , FIG. 5 is also reproduced below and annotated).



Second, neither of the Bersin balloons have a base that is a double layer of the balloon wall, a first wing wrapped continuously in a first direction circumferentially away from the base and about the central portion of the balloon, and a second wing wrapped continuously in a second direction, opposite the first direction, circumferentially away from the base and about the central portion of the balloon, as recited in claim 21. The sides of the “base” of the alleged “T-shaped structure”¹ are formed of adhesive, not the balloon wall. The “first wing” is not wrapped

¹ Applicant does not concede that Bersin discloses a “T-shaped” structure. There is no indication that Fig 5 is drawn to scale and that the adhesive actually extends far enough from the catheter to form the base of a T-shaped structure.

circumferentially about the central portion of the balloon and neither is the “second wing.” Since each arcuate structure is formed of a single balloon, the structure cannot be wrapped circumferentially about the central portion of the balloon. Each arcuate structure itself is the entire balloon. There is no “central portion” of the balloon in the contracted state. Instead, the “first wing” and the “second wing” wraps circumferentially about the catheter 12.

Even assuming, for the sake of argument only, that Bersin does in fact teach a structure according to the claimed invention, as the Examiner asserts, there is merely one such structure per balloon. Bersin does not teach a balloon having multiple T-shaped structures. Rather, Bersin teaches two balloons, each of which would have the structure.

Finally, the Examiner asserts in the Advisory Action that Bersin has been used “to show that a balloon structure can be folded in such a way that first and second wings are formed that extends [sic] in opposite directions from the base structure.” Advisory Action, p. 2. However, there is no teaching or suggestion that the Bersin balloon is folded into this configuration, and as discussed above there is no base structure in Bersin.

Thus, for at least these reasons, the rejection should be withdrawn because Butaric and Bersin, either alone or in combination, do not teach or suggest a balloon with multiple structures comprising a base that is a double layer of the balloon wall, a first wing wrapped continuously in a first direction circumferentially away from the base and about the central portion of the balloon to and terminating at a first terminating end, and a second wing wrapped continuously in a second direction, opposite the first direction, circumferentially away from the base and about the central portion of the balloon to and terminating at a second terminating end, wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure. The Examiner has not presented a *prima facie* case of obviousness, and therefore, the rejection should be withdrawn.

2. The proposed combination of Butaric and Bersin fails because there is no reasonable expectation of success to support such a combination.

The Examiner asserts that the folded configuration of the structures in Bersin “is advantageous because it allows the balloon structure to expand more evenly to its expanded condition with ‘unwrapping’ as would be required in the Butaric et al folded configuration.” Final

Office Action, p. 3, ¶ 4. However, none of the balloon structures in Bersin overlap, so it is not clear that the combination of the arrangement shown in Bersin with the balloon of Butaric would result in a successful, even expansion of the balloon as the Examiner asserts.

Because there is no overlapping structure in Bersin, there is no reasonable expectation that replacing the single-wing structures in Butaric with a balloon structure as shown in Bersin would result in more even expansion. Unlike the structure in Butaric, where the inflation medium has only one direction to go in each structure, the inflation medium in the present invention can go into either the first wing or the second wing. It is uncertain from the cited references that replacing the single wing structures in Butaric with the structures shown in Bersin would result in successful expansion of the balloon.

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). Here, there is no reasonable expectation that the combination of the “T-shaped structures” shown in Bersin with the wrapped balloon of Bersin would result in a successful, even expansion of the balloon.

Moreover, the combination of Butaric and Bersin is improper because the Examiner relies upon information gleaned solely from Applicant’s specification in supporting the proposed combination. *See* MPEP § 2145(X)(A). Such impermissible hindsight “must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” MPEP § 2142.

Neither reference teaches or suggests that even expansion can be obtained during inflation of overlapping “T-shaped structures,” as asserted in the Office Action. Rather, the present application discusses the disadvantages of a wrapped balloon, which imparts a rotational moment on the stent during expansion of the balloon and provides a structure where the stent contacts the balloon at the same points during expansion to promote even expansion. *See* Specification, p. 1, l. 16-21; p. 10, l. 9-15.

Because the cited references lack any teaching or suggestion of even expansion of the folded balloon structure, and because such reasoning is only present on the record in Applicant’s specification, the Examiner relies upon impermissible hindsight in presenting the combination of Butaric and Bersin.

For at least these reasons, Applicant contends that the combination is improper and respectfully requests that the rejection of claim 21 be withdrawn. Claims 22-24, 39, and 45 depend on claim 21. The rejection of those claims should be withdrawn.

3. The arguments presented above are also applicable to the other independent claims, claims 29 and 41.

Independent claim 29 recites, in pertinent part, a medical balloon in a contracted condition having:

“a central portion and a plurality of structures extending from the central portion, the structures each comprising, a base, wherein the base is a double layer of the balloon wall, a first wing extending continuously in a first direction circumferentially away from the base and around the central portion to and terminating at a first terminating end and a second wing extending continuously in a second direction circumferentially away from the base and around the central portion to and terminating at a second terminating end, such that there are a plurality of first wings and a plurality of second wings, wherein the first wings and the second wings extend around the central portion in opposite directions and wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure.”

The arguments presented above with respect to claim 21 are also applicable here.

As with claim 21, the Examiner proposes combining Butaric and Bersin. In particular, the Examiner alleges that Bersin teaches a balloon having multiple structures, where the structures when contracted have a T-shape with first and second wings extending in opposite directions. Final Office action, p. 3, ¶ 4. The Examiner asserts that it would have been obvious to one having ordinary skill in the art to have folded the structures of Butaric in the manner taught by Bersin to allow the balloon structure to expand more evenly to its expanded condition. *Id.*

Bersin does not teach the balloon structure of claim 29 having a base that is a double layer of the balloon wall, a first wing extending continuously in a first direction circumferentially away from the base and around the central portion, and a second wing extending continuously in a second direction circumferentially away from the base and around the central portion, and a second wing.

First, Bersin teaches two separate, diametrically opposed balloons 16 bonded to the outer surface of a catheter with adhesive 20. *See* col. 3, l. 66-68; col. 4, l. 1-16; FIGS. 1, 2 &

5. Bersin does not disclose a single balloon having two “T-shaped structures” in the contracted condition; each balloon has only one such structure. Thus, even if the references were combined, the resulting balloon would have only a single such structure.

Second, the structure disclosed by Bersin does not have a base in the form of a double layer of balloon wall. The sides of the “base” of the alleged “T-shaped structure” are formed of adhesive, not the balloon wall.

Third, Bersin does not have a wing extending circumferentially around the central portion of the balloon. Since each arcuate structure is formed of a single balloon, the structure cannot be wrapped circumferentially around the central portion of the balloon because the structure itself is the entire balloon. There is no “central portion” of the balloon in the contracted state. Instead, the “first wing” and the “second wing” wraps circumferentially around the catheter 12.

Furthermore, the proposed combination of Butaric and Bersin fails because there is no reasonable expectation of success to support such a combination. None of the balloon structures in Bersin overlap, so it is unclear that the combination of the arrangement shown in Bersin with the balloon of Butaric would result in a successful, even expansion of the balloon as the Examiner asserts. Because there is no overlapping structure in Bersin, there is no reasonable expectation that replacing the single-wing structures in Butaric with a balloon structure as shown in Bersin would result in more even expansion. Unlike the structure in Butaric, where the inflation medium has only one direction to go in each structure, the inflation medium in the present invention can go into either the first wing or the second wing. It is uncertain from the cited references that replacing the single wing structures in Butaric with the structures shown in Bersin would result in successful expansion of the balloon.

For at least these reasons, the rejection of claim 29 should be withdrawn and the claim should be allowed. Claims 30, 40, and 46 depend on claim 29. The rejection of those claims should therefore be withdrawn and the claims should be allowed. . Claim 47 depends on claim 41, and the rejection of that claim should be withdrawn.

Independent claim 41 recites, in pertinent part, a medical balloon in a contracted condition having:

a central portion and a plurality of structures extending from the central portion disposed thereabout, each structure comprising a base, wherein the base is a double layer of the balloon wall, a first wing wrapped continuously in a first direction about the central portion of the balloon to and terminating at a first terminating end and a second wing wrapped continuously in a second direction, opposite the first direction, about the central portion of the balloon to and terminating at a second terminating end, wherein the base of each of the structures is positioned in the second direction relative to the first terminating end and in the first direction relative to the second terminating end, such that each base of the plurality of structures is positioned circumferentially between the first terminating end and the second terminating end of the structure that corresponds to the base, and wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure.

As with claims 21 and 29, the Examiner proposes combining Butaric and Bersin. In particular, the Examiner alleges that Bersin teaches a balloon having multiple structures, where the structures when contracted have a T-shape with first and second wings extending in opposite directions. Final Office action, p. 3, ¶ 4. The Examiner asserts that it would have been obvious to one having ordinary skill in the art to have folded the structures of Butaric in the manner taught by Bersin to allow the balloon structure to expand more evenly to its expanded condition. *Id.* The arguments presented above with respect to claims 21 and 29 are also applicable here.

Bersin does not teach the balloon structure of claim 41 having a base that is a double layer of the balloon wall, a first wing wrapped continuously in a first direction about the central portion, and a second wing wrapped in a second direction about the central portion of the balloon.

First, Bersin teaches two separate, diametrically opposed balloons 16 bonded to the outer surface of a catheter with adhesive 20. *See* col. 3, l. 66-68; col. 4, l. 1-16; FIGS. 1, 2 & 5. Bersin does not disclose a single balloon having two “T-shaped structures” in the contracted condition; each balloon has only one such structure. Thus, even if the references were combined, the resulting balloon would have only a single such structure.

Second, the structure disclosed by Bersin does not have a base in the form of a double layer of balloon wall. The sides of the “base” of the alleged “T-shaped structure” are formed of adhesive, not the balloon wall. There is no indication that the adhesive actually extends far enough from the catheter to form the base of a T-shaped structure.

Third, Bersin does not have a wing extending circumferentially around the central

portion of the balloon. Since each arcuate structure is formed of a single balloon, the structure cannot extend circumferentially around the central portion of the balloon because the structure itself is the entire balloon. There is no “central portion” of the balloon in the contracted state. Instead, the “first wing” and the “second wing” wraps circumferentially about the catheter 12.

Furthermore, the proposed combination of Butaric and Bersin fails because none of the balloon structures in Bersin overlap, and thus it is unclear that the combination of the arrangement shown in Bersin with the balloon of Butaric would result in a successful, even expansion of the balloon as the Examiner asserts. Because there is no overlapping structure in Bersin, there is no reasonable expectation that replacing the single-wing structures in Butaric with a balloon structure as shown in Bersin would result in more even expansion. Unlike the structure in Butaric, where the inflation medium has only one direction to go in each structure, the inflation medium in the present invention can go into either the first wing or the second wing. It is uncertain from the cited references that replacing the single wing structures in Butaric with the structures shown in Bersin would result in successful expansion of the balloon.

4. With respect to claims 45-47, the combination of Butaric and Bersin fails to teach that the entirety of either the first wing or the second wing is prone and face to face without obstruction to the material of the balloon wall of the central portion.

Claims 45 depends from independent claim 21, claim 46 depends from independent claim 29, and claim 47 depends from independent claim 41. Each of these dependent claims recites that:

“when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the structures is prone and face to face without obstruction to the material of the balloon wall of the central portion.”

As shown in FIG. 12, (reproduced below) the second wing 118b is prone and face to face without obstruction to the material of the balloon wall of the central portion 112

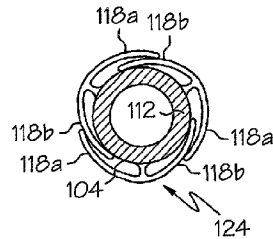
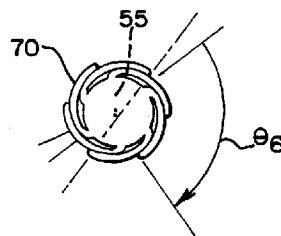


FIG. 12

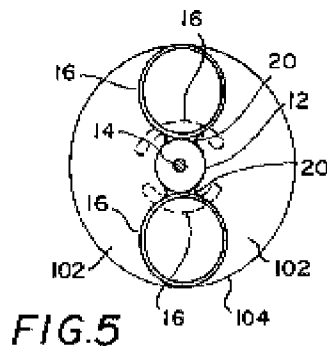
The Examiner asserts that “the balloon of Butaric et al. combined with Bersin shows the wings prone to the wall of the central portion without obstruction.” Final Office Action, p. 3, ¶ 6. However, neither Butaric nor Bersin teach or suggest wings that are prone and face to face without obstruction to the material of the balloon wall of the central portion.

In Butaric, the wing 70 is prone and face to face with an adjacent wing 70, not the material of the balloon wall of the “central portion.” See FIG. 6B (reproduced below).

FIG.6B



In Bersin, the wings are not prone and face to face with the central portion of the balloon. See FIG. 5 (reproduced below). As discussed above, Bersin does not have a central portion in the contracted state. Regardless of whether the wings are prone to the catheter 12, they are not prone to a central portion of the balloon.



For at least these reasons, Butaric and Bersin, either alone or in combination, fail to teach and suggest all of the limitations of the claims. Therefore, the rejection of claims 45-47 should be withdrawn, and the claims should be allowed.

Argument Conclusion

Based on at least the foregoing arguments, Applicants respectfully submit that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the rejected claims. Accordingly, Applicants respectfully request that the Board reverse the Examiner's rejections under 35 U.S.C. § 103(a).

Respectfully submitted,

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(viii) Claims Appendix

1-20. (Cancelled)

21. A medical balloon, wherein the medical balloon has a first end, a second end and a body portion longitudinally between the first end and the second end, and a balloon wall, the balloon having a contracted condition and is expandable to an expanded condition, wherein, when the medical balloon is in its expanded state, the balloon wall being formed of a material and has an inner surface facing inward and an outer surface facing outward, the medical balloon in its contracted condition having a central portion and a plurality of structures formed in the body portion and extending from the central portion disposed thereabout, each structure comprising a base, wherein the base is a double layer of the balloon wall, a first wing wrapped continuously in a first direction circumferentially away from the base and about the central portion of the balloon to and terminating at a first terminating end and a second wing wrapped continuously in a second direction, opposite the first direction, circumferentially away from the base and about the central portion of the balloon to and terminating at a second terminating end, wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure and wherein, when the medical balloon is in its expanded condition, the body portion of the medical balloon has a circular cross- section in the location of the plurality of structures.

22. The medical balloon of claim 21, wherein there are at least three structures extending from the central portion.

23. The medical balloon of claim 22 wherein the first and second wings alternate with one another about the central portion of the balloon.

24. The medical balloon of claim 23, wherein the structures are T-shaped structures extending from the central portion of the balloon.

25. (Withdrawn) The medical balloon of claim 23, at least one of the structures further comprising a third wing and fourth wing, both extending from the base and about the central portion, wherein the third wing is positioned between the first wing and the central portion and the fourth wing is positioned between the second wing and the central portion.

26-28. (Cancelled).

29. A medical balloon, wherein the medical balloon has a balloon wall, a contracted condition and is expandable to an expanded condition, wherein, when the medical balloon is in its expanded condition, the balloon wall being formed of a material and has an inner surface facing inward and an outer surface facing outward and has a circular cross-section, the medical balloon in its contracted condition having a central portion and a plurality of structures extending from the central portion, the structures each comprising, a base, wherein the base is a double layer of the balloon wall, a first wing extending continuously in a first direction circumferentially away from the base and around the central portion to and terminating at a first terminating end and a second wing extending continuously in a second direction circumferentially away from the base and around the central portion to and terminating at a second terminating end, such that there are a plurality of first wings and a plurality of second wings, wherein the first wings and the second wings extend around the central portion in opposite directions and wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure.

30. The medical balloon of claim 29 wherein the structures are T-shaped or V-shaped.

31-38 (Cancelled).

39. The medical balloon of claim 21, wherein, when the medical balloon is expanded to its expanded condition, the first wings and second wings disappear.

40. The medical balloon of claim 29, wherein, when the medical balloon is expanded to its

expanded condition, the plurality of first wings and the plurality of second wings disappear.

41. A medical balloon having a balloon wall, a contracted condition and is expandable to an expanded condition, wherein, when the medical balloon is in its expanded state, the medical balloon has a circular cross-section along its entirety and the balloon wall being formed of a material and has an inner surface facing inward and an outer surface facing outward, the medical balloon in its contracted condition having a central portion and a plurality of structures extending from the central portion disposed thereabout, each structure comprising a base, wherein the base is a double layer of the balloon wall, a first wing wrapped continuously in a first direction about the central portion of the balloon to and terminating at a first terminating end and a second wing wrapped continuously in a second direction, opposite the first direction, about the central portion of the balloon to and terminating at a second terminating end, wherein the base of each of the structures is positioned in the second direction relative to the first terminating end and in the first direction relative to the second terminating end, such that each base of the plurality of structures is positioned circumferentially between the first terminating end and the second terminating of the structure that corresponds to the base, and wherein each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure.

42. (Cancelled)

43. (Withdrawn) The medical balloon of claim 29, at least one of the structures further comprising a third wing and fourth wing, both extending from the base and about the central portion, wherein the third wing is positioned between the first wing and the central portion and the fourth wing is positioned between the second wing and the central portion.

44. (Withdrawn) The medical balloon of claim 41, at least one of the structures further comprising a third wing and fourth wing, both extending from the base and about the central portion, wherein the third wing is positioned between the first wing and the central portion and the fourth wing is positioned between the second wing and the central portion.

45. The medical balloon of claim 21, when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the structures is prone and face to face without obstruction to the material of the balloon wall of the central portion.

46. The medical balloon of claim 29, when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the structures is prone and face to face without obstruction to the material of the balloon wall of the central portion.

47. The medical balloon of claim 41, when the balloon is in its contracted condition, the entirety of either the first wing or the second wing of each of the structures is prone and face to face without obstruction to the material of the balloon wall of the central portion.

(ix) Evidence Appendix
None

- (x) **Related Proceedings Appendix**
None